



# FDA Approves First Ever MSC Therapy

CYP | CYNATA THERAPEUTICS LTD | HEALTHCARE | BIOTECHNOLOGY

PRICE  
**0.20/sh**

TARGET PRICE  
**0.67/sh**  
(UNCHANGED)

RECOMMENDATION  
**SPECULATIVE BUY**  
(UNCHANGED)

## Event

In a major announcement, the US Food and Drug Administration (FDA) has approved the first ever Mesenchymal Stem Cell (MSC) therapy. Press release [here](#).

Ryoncil (remestemcel-L-rknd), developed by Mesoblast (ASX: MSB), is now approved for the treatment of pediatric steroid-refractory acute graft-versus-host disease.

## Impact

This outcome is undoubtedly a significant positive for the MSC field, including CYP, as it establishes a precedent of the FDA approving an MSC therapy. We believe this development could give potentially interested commercial partners and investors the confidence to now enter the MSC space.

Importantly, Ryoncil does not compete with CYP-001. Its approval is confined to paediatric steroid-resistant acute GvHD – a small subset of acute GvHD estimated to number in the hundreds of patients, whereas CYP-001 is targeted at adults, which represents a significantly larger market.

Moreover, while the FDA may have been open to approving Ryoncil for this ultra-rare condition, in light of the significant unmet need (no approved treatment for paediatric patients), it remains to be seen whether Mesoblast faces greater challenges in pursuing approval for adult steroid-resistant acute GvHD or other broader indications. We would expect challenges to arise from conventional manufacturing methods which rely on an ongoing supply of donor cells and extensive cell expansion. As we discussed in our initiation (link [here](#)), this approach leads to variable product consistency and potency, alongside scalability issues.

In contrast, CYPs technology uses induced pluripotent stem cells (iPSCs) to produce a virtually unlimited, consistent, and potent supply of MSCs from a single donor, effectively overcoming the limitations of conventional manufacturing processes.

CYP's lead asset, CYP-001, is currently in a phase 2 clinical trial for acute graft versus host disease (aGvHD). The drug is supported by impressive early results and presents a rapid pathway to market for CYP to validate its platform.

## Action

### We maintain our Speculative Buy Recommendation and \$0.67 Price Target

Mesoblast (MSB), a key ASX-listed peer, presents a compelling case study of the potential value upside in CYP. Particularly following its recent FDA approval.

From when the FDA notified Mesoblast it could re-submit Ryoncil's BLA application to its FDA approval, the company's market cap increased by \$3.2 billion to approximately \$3.5 billion on the day (Figure 1). This is a stark contrast to CYP's \$46 million market cap.

While we acknowledge Mesoblast is more advanced than CYP, the current valuation gap between the two company's (based on the market cap ratio) is at its widest in 10 years (Figure 2). Ultimately, we believe CYP holds the superior technology.

## Catalysts

Phase 2 aGvHD Enrolment Completion - Q2 CY25/ Phase 2 aGvHD Study Results - Q4 CY25/Phase 1/2 Kidney Transplant Results - Q1/2 CY25/Phase 3 Osteoarthritis (OA) Results - Q1/2 CY26 (Figure 3).

## Analyst

Seth Lizee

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Share Price	0.20	A\$/sh	
Price Target	0.67	A\$/sh	
Riskied Valuation	0.67	A\$/sh	
Unriskied Valuation	1.33	A\$/sh	
WACC	15%	%	
TGR	2%	%	
Shares on issue	230.7	m,dil	
Market Cap	46.1	A\$m	
Enterprise Value	31.0	A\$m	
Debt (inc. leases)	0.0	A\$m	
Cash (pro forma)	14.3	A\$m	
Unpaid capital*	0.9	A\$m	
*in-the-money			
Key Metrics	25F	26F	27F
Revenue (A\$m)	1.7	16.8	19.7
EBITDA (A\$m)	-6.6	-18.1	-7.6
EBIT (A\$m)	-6.8	-18.4	-7.8
NPAT (A\$m)	-6.8	-18.4	-7.8
Gross CF (A\$m)	-6.6	-18.1	-7.6
Capex (A\$m)	0.0	0.0	0.0
Op. FCF (A\$m)	-6.6	-16.7	-8.9
EPS (Ac)	-3.0	-8.1	-3.5
Revenue Growth	-0.4	8.7	0.2
PER (x)	na	na	na
EV/EBITDA (x)	na	na	na
EV/Revenue (x)	17.8	1.8	1.6
Net Cash	7.7	31.0	22.1

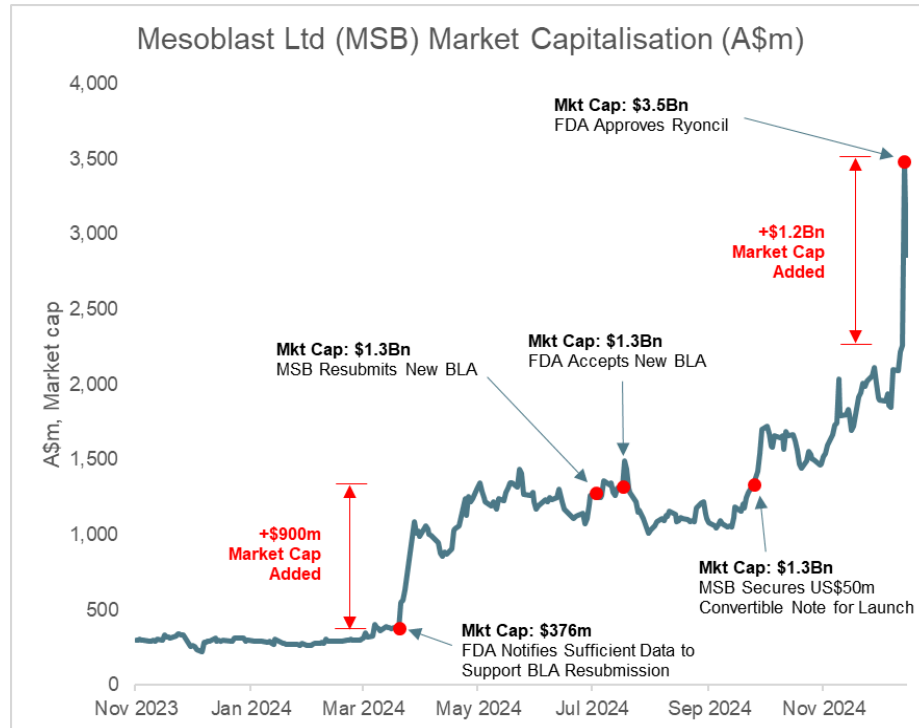
## Performance



Source: IRESS

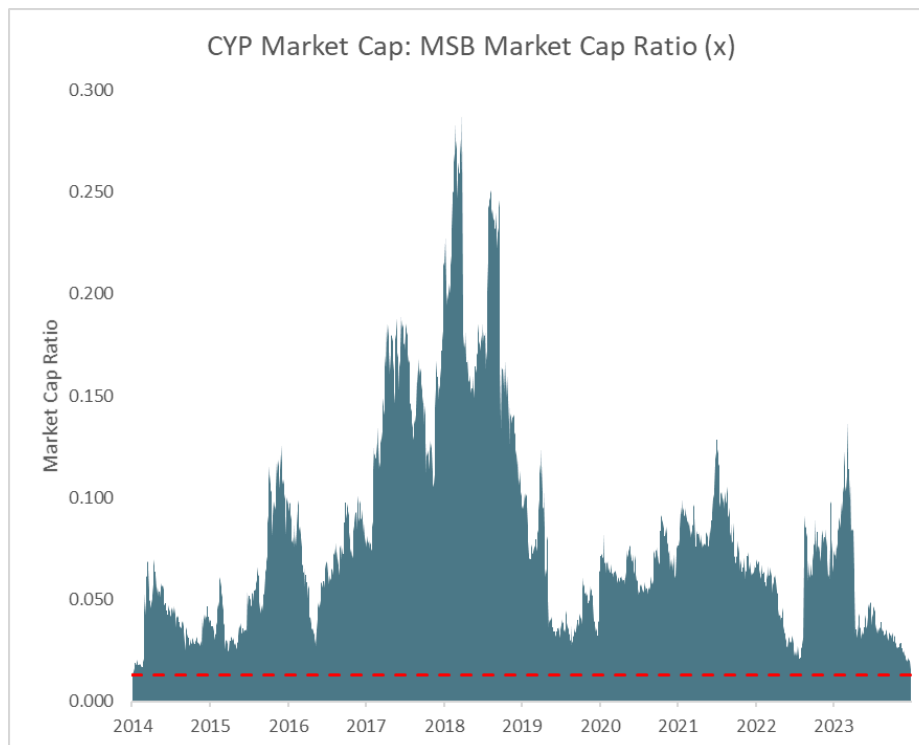
Income Statement	25F	26F	27F	28F
Milestone Payments	0.0	16.4	16.4	0.0
Royalty Income	0.0	0.0	0.0	0.0
Other (incl. R&D)	1.7	0.4	3.3	2.2
<b>Revenue</b>	<b>1.7</b>	<b>16.8</b>	<b>19.7</b>	<b>2.2</b>
(-) R&D	-4.7	-31.3	-23.4	-7.8
(-) SG&A	-3.6	-3.7	-3.8	-4.0
<b>EBITDA</b>	<b>-6.6</b>	<b>-18.1</b>	<b>-7.6</b>	<b>-9.6</b>
(-) D&A	-0.2	-0.2	-0.2	-0.2
<b>EBIT</b>	<b>-6.8</b>	<b>-18.4</b>	<b>-7.8</b>	<b>-9.8</b>
(-) Finance	0.0	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0	0.0
<b>PBT</b>	<b>-6.8</b>	<b>-18.4</b>	<b>-7.8</b>	<b>-9.8</b>
(-) Tax	0.0	0.0	0.0	0.0
<b>NPAT</b>	<b>-6.8</b>	<b>-18.4</b>	<b>-7.8</b>	<b>-9.8</b>
Cash Flow Statement	25F	26F	27F	28F
<b>NPAT</b>	<b>-6.8</b>	<b>-18.4</b>	<b>-7.8</b>	<b>-9.8</b>
(+) D&A	0.2	0.2	0.2	0.2
(+) Non-cash expenses	0.0	0.0	0.0	0.0
(-) Leases	0.0	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0	0.0
<b>Gross Cash Flow</b>	<b>-6.6</b>	<b>-18.1</b>	<b>-7.6</b>	<b>-9.6</b>
(-) Capital Expenditure	0.0	0.0	0.0	0.0
(-) Net Working Capital	0.0	1.4	-1.3	0.2
<b>Operating Free Cash Flow</b>	<b>-6.6</b>	<b>-16.7</b>	<b>-8.9</b>	<b>-9.4</b>
(-) Acquisition	0.0	0.0	0.0	0.0
(-) Dividend	0.0	0.0	0.0	0.0
(+) Disposal	0.0	0.0	0.0	0.0
(+) Equity Issue	8.1	40.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0	0.0
<b>Net Cash Flow</b>	<b>1.5</b>	<b>23.3</b>	<b>-8.9</b>	<b>-9.4</b>
<b>BoP Net Cash / (Debt)</b>	<b>6.2</b>	<b>7.7</b>	<b>31.0</b>	<b>22.1</b>
(+/-) Net Cash Flow	1.5	23.3	-8.9	-9.4
(+/-) AASB16	0.0	0.0	0.0	0.0
<b>EoP Net Cash / (Debt)</b>	<b>7.7</b>	<b>31.0</b>	<b>22.1</b>	<b>12.7</b>
Balance Sheet	25F	26F	27F	28F
Cash	7.7	31.0	22.1	12.7
Receivables	0.1	2.1	2.4	0.3
Prepayments	0.2	0.2	0.2	0.2
<b>Total Current Assets</b>	<b>8.1</b>	<b>33.3</b>	<b>24.7</b>	<b>13.2</b>
Intangibles	1.6	1.4	1.2	1.1
<b>Total Non Current Assets</b>	<b>1.6</b>	<b>1.4</b>	<b>1.2</b>	<b>1.1</b>
<b>Total Assets</b>	<b>9.7</b>	<b>34.7</b>	<b>25.9</b>	<b>14.3</b>
Payables	1.0	4.3	3.4	1.5
Provisions	0.2	0.2	0.2	0.2
<b>Total Current Liabilities</b>	<b>1.2</b>	<b>4.5</b>	<b>3.6</b>	<b>1.7</b>
<b>Total Liabilities</b>	<b>1.2</b>	<b>4.5</b>	<b>3.6</b>	<b>1.7</b>
<b>Net Assets</b>	<b>8.5</b>	<b>30.2</b>	<b>22.4</b>	<b>12.6</b>
Issued Capital	89.7	129.7	129.7	129.7
Reserves	7.9	7.9	7.9	7.9
Retained Earnings	-89.1	-107.5	-115.3	-125.0
<b>Total Equity</b>	<b>8.5</b>	<b>30.2</b>	<b>22.4</b>	<b>12.6</b>
Performance Ratios	25F	26F	27F	28F
<b>Growth</b>				
Revenue Growth (%)	-36%	868%	17%	-89%
EBITDA Growth (%)	-31%	176%	-58%	26%
EBIT Growth (%)	-30%	169%	-58%	25%
NPAT Growth (%)	-30%	169%	-58%	25%
<b>Margin</b>				
EBITDA Margin (%)	-378%	-108%	-39%	-441%
EBIT Margin (%)	-392%	-109%	-40%	-448%
PBT Margin (%)	-392%	-109%	-40%	-448%
NPAT Margin (%)	-392%	-109%	-40%	-448%
Effective Tax Rate (%)	0%	0%	0%	0%
<b>Liquidity</b>				
Capex/depreciation (x)	0	0	0	0
Current ratio (x)	6.9	7.3	6.9	7.9
Quick ratio (x)	8.3	7.7	7.3	9.0
Receivable days	23.7	45.0	45.0	45.0
Payable days	41.8	45.0	45.0	45.0
<b>Risk Measures</b>				
Dividend Cover (x)	na	na	na	na
Payout ratio (%)	0%	0%	0%	0%
Net interest cover (x)	na	na	na	na
Net debt/equity (%)	-91%	-103%	-99%	-101%
<b>Returns</b>				
ROIC (%)	na	na	na	na
ROA (%)	na	na	na	na
ROE (%)	na	na	na	na
Share Data/Valuation	25F	26F	27F	28F
<b>Share Data</b>				
Issued shares (m)	225.9	225.9	225.9	225.9
Weighted ave shares (m)	225.9	225.9	225.9	225.9
Fully diluted shares (m)	260.6	260.6	260.6	260.6
Basic EPS (c)	-3.0	-8.1	-3.5	-4.3
YoY change (%)	na	na	na	na
Fully diluted EPS (c)	-2.6	-7.0	-3.0	-3.7
YoY change (%)	na	na	na	na
Fully dil norm EPS (c)	-2.6	-7.0	-3.0	-3.7
YoY change (%)	na	na	na	na
Dividend/share (c)	0.0	0.0	0.0	0.0
Franking (%)	na	na	na	na
Gross cash flow/share (c)	-2.9	-8.0	-3.4	-4.2
NBV/share (c)	3.8	13.3	9.9	5.6
NTA/Share (c)	3.1	12.7	9.4	5.1
<b>Share Data</b>				
PER (Basic) (x)	na	na	na	na
PER (Fully diluted) (x)	na	na	na	na
PER (Fully dil, norm) (x)	na	na	na	na
P/CFPS (x)	na	na	na	na
Price/NBV (x)	5.3	1.5	2.0	3.6
Price/NTA (x)	6.6	1.6	2.1	3.9
Dividend Yield (%)	0.0	0.0	0.0	0.0
EV/EBITDA (x)	na	na	na	na
EV/EBIT (x)	na	na	na	na
EV/Revenue (x)	17.8	1.8	1.6	14.2

Figure 1: Mesoblast Ltd (ASX: MSB) Market Capitalisation



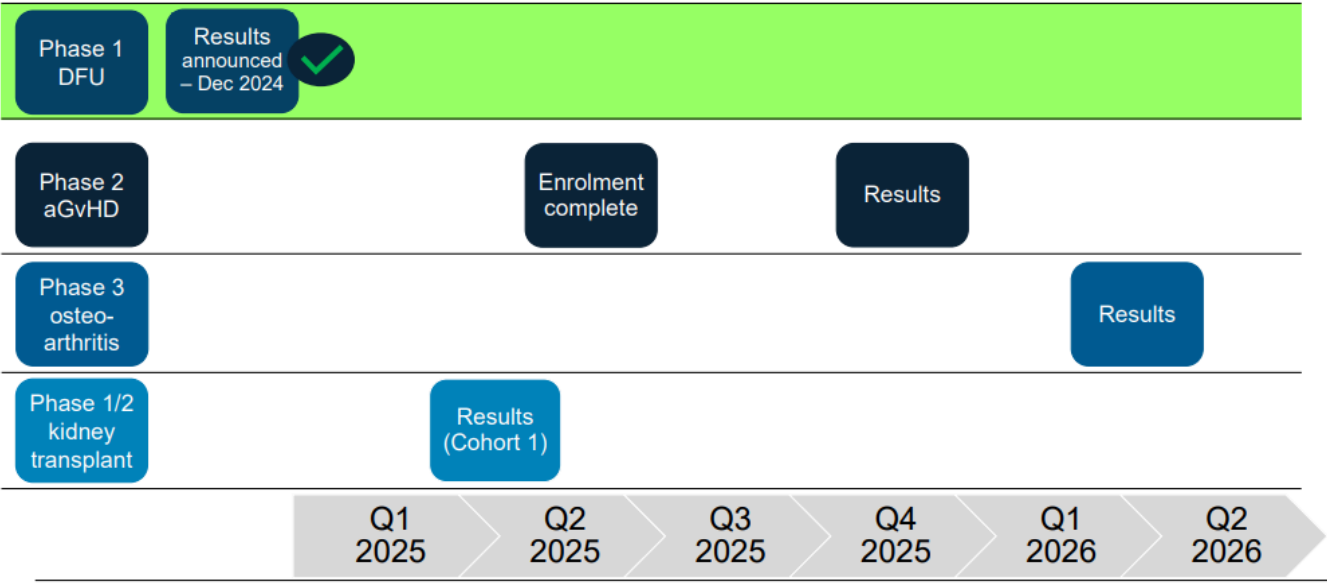
Source: Bloomberg LP, Company Announcements, EH analysis

Figure 2: Ratio of Cynata Therapeutics (ASX: CYP) Market Capitalisation to Mesoblast Ltd (ASX: MSB) Market Capitalisation



Source: Bloomberg LP, EH analysis

Figure 3: Upcoming Catalysts



Source: Company presentation

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No part of our compensation was, is or will be directly or indirectly, related to the specific recommendations or views expressed by the authoring Analyst in this research, nor has there been any adverse or undue influence on the Analyst in the preparation of this report.

## Company disclosures

The companies and securities mentioned in this report, include:

Cynata Therapeutics Ltd (CYP) | Price 0.20 | Target price 0.67 | Recommendation Speculative Buy;

*Price, target price and rating as at 20 December 2024 (\* not covered)*

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The analyst declares that they have a beneficial interest in: Cynata Therapeutics Ltd (CYP)

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